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09/975,317	10/12/2001	Alan David Watson	WATS3001/REF/C	8178
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Richard E. Fichter BACON & THOMAS, PLLC Fourth Floor 625 Slaters Lane Alexandria, VA 22314-1176			JONES, DAMERON LEVEST	
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/975,317

Filing Date: October 12, 2001

Appellant(s): WATSON ET AL.

Richard E Fichter

For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 1/12/07 appealing from the Office action  
mailed 7/13/06.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,190,744	Rocklage	3-1993
4,889,931	Rocklage	12-1989
5,632,968	Goldenberg	5-1997

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims.

I. Claims 76, 77, 79-81, 84-86, 88-93, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocklage (US Patent No. 5,190,744) in view of Rocklage (US Patent No. 4,889,931).

**Rocklage '744** discloses a method of detecting myocardial ischemia in a subject comprising administering a contrast medium comprising a manganese complex and subjecting the subject to a fast MRI technique to detect abnormal blood flow (see abstract). Methods of fast MRI, as claimed, are disclosed in column 2 (lines 10-32). Manganese chelates are disclosed in column 4 (line 55) and claim 26 of the patent. The dosages are within the claimed dosages (column 5, lines 38-61). The methods of Rocklage '744 are for imaging myocardial ischemia (column 2, lines 33-38 and column 8, lines 17-57). In addition, Rocklage '744 discloses that various known chelating agents may be employed (column 4, lines 19-49). However, Rocklage '744 fails to specifically disclose the use of the same contrast agents as instantly claimed (e.g., manganese complexes, such as that in newly added claim 96), but does disclose the use of its contrast agents for cardiovascular system imaging.

**Rocklage '931** discloses MRI contrast agents comprising manganese chelates which are highly stable chelating agents and thus are suitable for method of imaging (column 2, lines 1-40). In addition, the reference discloses that manganese is the preferred metal for such MRI complexes (column 3, lines 34-36). The contrast agents include manganese complexes of DPDP (column 4, lines 47-50). It should be noted

that these chelates are the same as those of the instant invention (see column 3, formula I and columns 4-5, bridging paragraph).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rocklage '744 using the teachings of Rocklage '931 and generate a method of distinguishing viable myocardial tissue from necrotic (infarcted) tissue in a subject as set forth in independent claim 96 because: (1) both references disclose the use of contrast agents for imaging the cardiovascular system; and (2) the chelating agents disclosed by Rocklage '931 encompass those of the instant invention. (3) Also, a skilled practitioner in the art would recognize that imaging the heart generates an image of the complete heart, so while the entire heart will be imaged, the intensity of the contrast agent absorb would vary depending upon the type of tissue (i.e., infarcted and/or healthy) present. For example, the skilled practitioner would recognize that the properties of infarct and healthy tissue are different so, the outcome from administering a composition would differ such that both while both tissues would be imaged, one would be able to distinguish between the two based on the intensity of absorbed contrast agent. (4) In addition, a skilled practitioner in the art would recognize that since the compositions administered to the subject are the same, the properties of those compositions would be the same as well. Thus, if Applicant's contrast agent is capable of distinguishing between viable and necrotic myocardial tissue, the contrast agents of the prior art would also possess those properties. (5) Furthermore, it is noted that in Rocklage '744, it is disclosed that MRI using magnetic susceptibility contrast agents allows one to determine the existence and

location of a perfusion deficit and detect the degree or severity, and if possible the onset and duration, of abnormalities or variations in a quantifiable manner when a subject is administered a contrast agent (abstract; column 1, lines 7-12 and 26-55).

Appellant asserts that the instant invention is directed to a method of distinguishing viable myocardial tissue from necrotic (infracted) tissue whereas the cited prior art (Rocklage '744) is concerned with the detection of cerebral ischemia. In addition, Appellant asserts that even though Rocklage '744 teaches the same method would be useful in the detection of coronary ischemia, the myocardium and coronary arteries are different parts of the heart. Thus, it is Appellant's position that there is no motivation in Rocklage '744 which suggests the claimed invention or suggests there is a likelihood of applying the method of Rocklage '744 to the instant invention. Also, Appellant asserts that the dosage amounts and the  $K_a$  value of claim 96 are not disclosed by the cited prior art. Appellant asserts that the cited prior art does not distinguish between irreparable and repairable cells. Thus, it would not have been obvious to modify the teachings of Rocklage '744 with Rocklage '931.

Based on the reasoning which would motivate one of ordinary skill in the art to combine the references, a skilled practitioner in the art would recognize that imaging the heart generates an image of the complete heart and while the entire heart will be imaged, the intensity of the contrast agent absorb would vary depending upon the type of tissue (i.e., infarcted and/or healthy) present. Thus, one would be able to distinguish between healthy and infarcted tissue. For example, the skilled practitioner would recognize that the properties of infarct and healthy tissue are different so, the outcome

from administering a composition would differ such that both while both tissues would be imaged, one would be able to distinguish between the two based on the intensity of absorbed contrast agent. Furthermore, a skilled practitioner in the art would recognize that since the compositions administered to the subject are the same/similar, the properties of those compositions would be the same as well. In other words, since a compound/composition is inseparable from its properties since Appellant's contrast agent is capable of distinguishing between viable and necrotic myocardial tissue, the contrast agents of the prior art would also possess those properties ( $K_a$  value and distinguishing between infarcted and healthy tissue). Furthermore, it is noted that in Rocklage '744, it is disclosed that MRI using magnetic susceptibility contrast agents allows one to determine the existence and location of a perfusion deficit and detect the degree or severity, and if possible the onset and duration, of abnormalities or variations in a quantifiable manner when a subject is administered a contrast agent (abstract; column 1, lines 7-12 and 26-55). Thus, the skilled practitioner in the art would recognize that one can determine the location and existence of healthy and infarct tissue by administering a composition of the prior art to a subject.

Appellant asserts that the mechanisms by which Rocklage '744 and the instant invention operate are different. The method of Rocklage '744 can only be used or identify and/or monitor abnormal or modified blood flow whereas the instant invention is used for imaging myocardial tissue. In addition, Appellant asserts that the instant invention distinguishes between viable and infarcted tissue whereas the cited prior art does not. Also, Appellant asserts that even though Rocklage '744 discloses that Mn is

one of the several possible metals, there is nothing to lead one to this particular metal instead of Dy which is preferred. Also, Appellant asserts that only Dy-contrast agents are only specifically disclosed in Rocklage '744, not contrast agents containing Mn. As a result, Appellant has concluded that the Examiner used impermissible hindsight in combining the references.

While Applicant inserts that the mechanisms of the prior art and those of the instant invention are different, if one is administering the same compound/composition, then the skilled artisan would recognize that the mechanisms will be the same. Why? The skilled artisan would recognize that one cannot separate the properties of one composition from another when the compositions administered to the subject are exactly the same. Furthermore, Rocklage '744 is considered for its teachings as a whole, not for its teachings on a preferred embodiment. Thus, since Rocklage '744 teaches the equivalents of the metals Dy and Mn, it does not matter that only Dy-contrast agents are disclosed in the examples. The fact of the matter is that motivation is present in the prior art since Rocklage '744 discloses that both Dy and Mn are particularly suitable paramagnetic metal ions for chelation (column 4, lines 50-58). As a result, the Examiner did not use hindsight in combining the references, but reviewed the references and drew conclusions based upon what is disclosed in the reference.

II. Claims 77, 78, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocklage (US Patent No. 5,190,744) in view of Goldenberg (US Patent No. 5,632,968).

**Rocklage '744** (also see discussion above) discloses that various varieties of echo planer imaging are suitable with their invention (column 2, lines 19-23), but fails to specifically disclose that the echo imaging is an inversion recovery echo imaging method.

**Goldenberg** disclose method of imaging cardiovascular lesion and teaches that inversion recovery is a well-known and equivalent method of spin-echo MRI (column 13, lines 23-48).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method disclosed by Rocklage '744 and use inversion-recovery spin-echo MRI as the spin echo MRI procedure because it is well known in the art, as indicated by Goldenberg, that such technique is useful and an equivalent method of spin-echo MRI.

Appellant's assertions are the same as those set forth in section I above for Rocklage '744 and that Goldenberg does not make up for the deficiencies of Rocklage '744.

Appellant's assertions were addressed in section I above. Furthermore, it should be noted that Goldenberg was cited for its teachings of the equivalence of spin-echo MRI and inversion recovery, not for all the teachings disclosed by Rocklage '744 (distinguishing infarcted and healthy tissue and administering the same compound/composition as set forth in the instant invention).

**(10) Response to Argument**

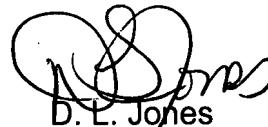
No additional response is need because the issues raised by Appellant were fully responded to under "Grounds of Rejection" above.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

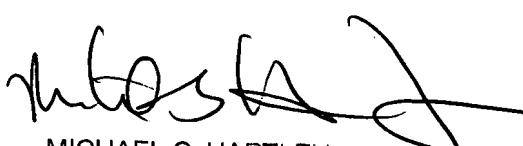
Respectfully submitted,

  
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